K090869

Medtronic

AUG 27 2009

510(k) Summary

Date Prepared: August 11, 2009

Submitter: Medtronic Perfusion Systems
7611 Northland Drive
Minneapolis, MN 55428
Establish Registration Number: 2184009

Contact Person: Jessica Sixberry
Senior Regulatory Affairs Specialist
Phone: (763) 514-9849
Fax: (651) 367-1893
Email: jessica.m.sixberry@medtronic.com

Device Name and Classification:

Trade Name:	MiRCSP (Minimally Invasive Retrograde Coronary Sinus Perfusion) Auto and Manual Inflate Cannula
Common Name:	Cardiopulmonary bypass vascular catheter, cannula, or tubing
Regulation Number:	21 CFR 870.4210
Product Code:	DWF
Classification:	Class II

Predicate Devices

- Medtronic DLP Venous Perfusion Cannula with Cuff (K860149)
- Medtronic DLP Silicone RCSP Cannula with Auto-Inflate Cuff (K901074)
- RMI (Edwards Lifesciences) Steerable Retrograde Cardioplegia Cannula (K001565)
- Heartport (Edwards Lifesciences) Direct Arterial Cannula (previously known as StraightShot) (K994243)
- Heartport (Edwards Lifesciences) Endocoronary Sinus Catheter (K964248)
- Medtronic Cardioblate Gemini Device (K070311)

Device Description

MiRCSP Cannulae are single-use, sterile, nonpyrogenic devices designed to deliver cardioplegia through the coronary sinus in a retrograde manner, for periods up to six hours during cardiopulmonary bypass surgery. These devices are available in models that feature manual and auto inflating cuffs, and contain an aid in verification of cannula placement. The removable malleable stylet is used to provide stiffness and shape to the cannula body during insertion and features additional deflectability and rotation at the distal cannula tip to aid in placement into the coronary sinus. These cannulae have features that make them easier to use when minimally invasive surgical approaches are utilized (i.e., mini-sternotomy and right thorocotomy).

Model	Cannula Body Type	Introducer Type
94113TD	Manual-Inflate	Tip deflects away from slider
94113TDT	Manual-Inflate	Tip deflects toward slider
94533TD	Auto-Inflate	Tip deflects away from slider
94533TDT	Auto-Inflate	Tip deflects toward slider

Indications for Use

The MiRCSP cannula is intended for use during cardiopulmonary bypass for the delivery of cardioplegia retrograde through the coronary sinus for up to six hours. It is indicated for use during cardiac surgery for median sternotomy or minimally invasive (mini-sternotomy or right thoracotomy) access using direct, echocardiographic or fluoroscopic visualization techniques.

Comparison to Predicate Devices

MiRCSP Cannulae contain the same technological characteristics when compared to the existing Medtronic (MDT) retrograde cardioplegia delivery cannulae. These cannulae utilize the design features and materials of the Medtronic RCSP Models 94113 and 94533, including a removable stylet introducer with a malleable shaft to provide cannula shape and stiffness. The MiRCSP introducer features additional distal tip deflectability and rotation to further aid in cannula placement when used in conjunction with small incision surgical approaches (i.e. thoracotomies or mini-sternotomies). The cannulae bodies include enhanced visibility *in-vivo*.

- Intended Use: The MiRCSP Cannula has the same intended use as the Medtronic DLP Retrograde Coronary Sinus Perfusion Cannula with Manual-Inflating Cuff and Silicone Body, and DLP PVC Retrograde Coronary Sinus Perfusion Cannula with Auto-Inflate Cuff; with the addition of information regarding visibility and surgical procedure access.
- Principles of Operation and Technology:
    - MiRCSP Cannulae use the same technologies in operation as currently marketed manual and auto-inflating retrograde coronary sinus perfusion cannulae.
    - Temporary coronary sinus occlusion for delivery of retrograde cardioplegia and measurement of coronary sinus pressure are accomplished in the same manner.
    - MiRCSP Cannulae are also made from the same base materials as their MDT predicates.
    - Cannula introduction is accomplished in the same manner using a removeable, malleable stylet, fully contained within the cannula body.
    - The MiRCSP Cannula introducer also features the additional ability to deflect and rotate the distal portion of the cannula, *in-vivo*, to further aid in placement of the cannula into the coronary sinus. This uses similar technology as the RMI Steerable Retrograde Cannula.

- MiRCSP Cannulae are visible under ultrasound (TEE) and feature enhanced visibility under fluoroscopy in the distal tip area, to aid in placement verification. These features are also available with the Heartport Endocoronary Sinus Catheters.

- Performance: The MiRCSP Cannulae Models 94113TD, 94113TDT, 94533TD and 94533TDT were compared to previously cleared Medtronic RCSP Model 94113 and 94533, respectively, as predicates for performance characteristics. The comparisons demonstrated that these cannulae were substantially equivalent in performance.

Summary of Performance Data

Bench and animal testing were used to establish the performance characteristics of the modifications of this device from previously marketed MDT cannula devices. Clinical testing was not required to establish substantial equivalence. The following performance tests were conducted:

- Flow Rate Versus Pressure Drop
- Visibility Under Ultrasound and Fluoroscopic Visualization Techniques
- Structural Integrity (bonded joints and introducer)
- Biocompatibility Testing

Conclusion

Medtronic has demonstrated that the MiRCSP Cannula is substantially equivalent to the predicate devices based upon design, test results, and indications for use. Any noted differences do not raise new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

AUG 2 7 2009

Medtronic Perfusion Systems
c/o Ms. Jessica Sixberry
7611 Northland Drive
Minneapolis, MN 55432

Re: K090869
MiRCSP Cannula
Regulation Number: 21 CFR 870.4210
Regulation Name: Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass
Regulatory Class: Class II (two)
Product Code: DWF
Dated: August 11, 2009
Received: August 14, 2009

Dear Ms. Sixberry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Donna R. Vachuska

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K090869

Device Name: MiRCSP^{TM} (Minimally Invasive Retrograde Coronary Sinus Perfusion) Auto and Manual Inflate Cannula

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Prescription Use X OR Over-The-Counter Use _____
Per 21 CFR 801.109

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochner
(Division Sign-Off)
Division of Cardiovascular Devices
510(k) K090869